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August 24, 2007

BY E-FILING and HAND DELIVERY

The Honorable Mary Pat Thyng
United States Magistrate Judge
United States District Court
844 King Street
Wilmington, DE 19801

Re: *Roquette Frères v. SPI Pharma, Inc., et al.*
C.A. 06-540 (***)

Dear Judge Thyng:

We write to summarize, in preparation for the telephone conference scheduled for August 28 at 5:00 pm, three discovery disputes that Plaintiff Roquette Frères ("Roquette") has against Defendant SPI Pharma, Inc. ("SPI").

By way of background, Roquette filed this action against SPI on August 31, 2006, for infringement of Roquette's U.S. Patent No. 5,573,777. That patent covers, *inter alia*, mannitol that exhibits certain measured properties (i.e. friability, apparent density, particle size and dissolution rate). Roquette's patent also covers compositions that include such mannitol as an ingredient, as well as methods for mannitol preparation.

In its original Complaint (D.I. 1), and in its First and Second Amended Complaints (D.I. 9 and 67), Roquette alleges that SPI is and has been infringing one or more claims of Roquette's patent, and that "[i]nfringing products include, without limitation, MannogemTM EZ Spray Dried Mannitol." (emphasis added).

In its Answer (D.I. 79), SPI counterclaims, without any specificity, that "[t]he claims of the '777 patent are invalid for failure to satisfy the conditions of patentability specified in Title 35, U.S.C. §§ 101, 102, 103 and 112."

SPI's co-defendants ("the Drytec Entities") filed a joint motion to dismiss, alleging lack of personal jurisdiction, which has been fully briefed and is pending before the Court. Meanwhile, Roquette has sought discovery from SPI through interrogatories, document

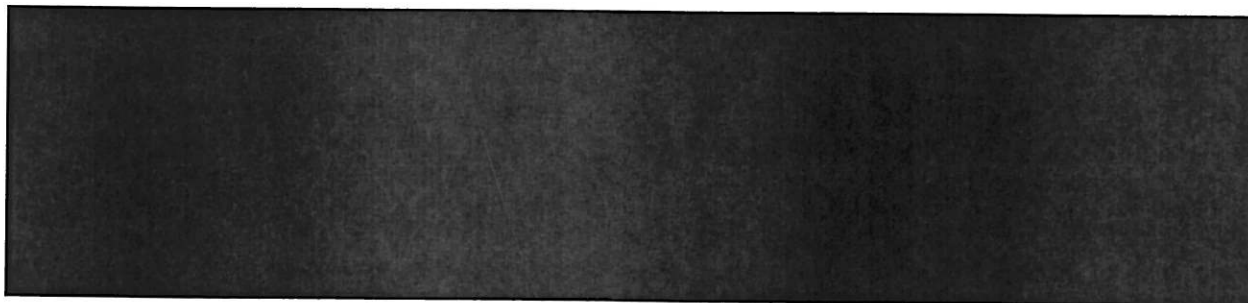
The Honorable Mary Pat Thyng
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requests, letter correspondence, and meet-and-confer conferences, most recently on August 17, 2007.


Roquette requested, and SPI refuses to provide, relevant information in the following three categories.¹

I. Information Regarding SPI's Mannitol Products Other Than MannogemTM EZ

Roquette's patent discloses that the claimed mannitol products result from spray drying. SPI's MannogemTM EZ was previously made by the Drytec Entities through spray drying, and now is manufactured by SPI in the U.S., again through spray drying. Roquette obtained and tested samples of MannogemTM EZ manufactured on the Drytec Entities' spray drying facility, and determined that the samples infringed claims of Roquette's patent.



Roquette considers in good faith that the other spray dried mannitols produced by or for SPI, and especially those spray dried mannitols that were manufactured on the same Drytec facility, or are now manufactured by SPI on a same or similar spray drying system as MannogemTM EZ, are likely to infringe.

In addition to SPI's other spray dried mannitols, Roquette seeks SPI's information regarding its compositions that incorporate those spray dried mannitols. 



Roquette requested that SPI provide information regarding the physical and chemical properties of each of its spray dried mannitol products. SPI's refusal to provide any information regarding any product other than MannogemTM EZ is unwarranted and contrary to the Federal Rules.

¹ We attach the relevant formal correspondence, which consists of Roquette's July 20th letter request, SPI's July 30th response, and Roquette's August 17th letter summarizing the parties' August 17th meet and confer conference, as Exhibit 1.

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II. SPI's Sales and Profit Data

Roquette needs SPI's comprehensive sales and profit data to calculate all of Roquette's damages. SPI identified in its July 30, 2007 letter certain SPI documents related to MannogemTM EZ sales, and represented during the August 17, 2007 conference that the identified documents are complete through May 2007 and are sufficient to calculate damages with respect to MannogemTM EZ.

Roquette accepted SPI's representation, reserving its right to seek documentary information from which the MannogemTM EZ sales and profit data were compiled.

However, Roquette requires SPI's sales and profit information for all of SPI's spray dried mannitol products that Roquette believes in good faith are likely to infringe. SPI's refusal to provide any sales and profit information regarding any product other than MannogemTM EZ is again unwarranted and contrary to the Federal Rules.

III. SPI's Invalidity Contentions

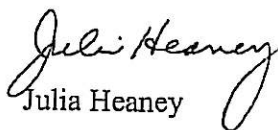
As noted, SPI counterclaims that Roquette's patent is invalid, but fails to allege any supporting fact or contention except to reference the patents actually considered by the patent examiner, along with a few foreign counterparts to those patents. SPI has refused Roquette's requests for the factual and legal bases of SPI's invalidity contentions. Obviously, Roquette needs to know the bases of SPI's invalidity contentions if it is to have a meaningful opportunity to defend. SPI states that it will provide information relating to invalidity at some unspecified later date.

SPI has complained that Roquette's identification of SPI's infringement is insufficient, although Roquette has identified MannogemTM EZ as an infringing product, asserted infringement of at least Claim 1 of the '777 patent, and provided test results showing that SPI's MannogemTM EZ falls within the limits set forth in Claim 1.

To move this issue forward, Roquette proposed that the parties simultaneously exchange SPI's detailed invalidity contentions and a detailed claim chart of infringement from Roquette. SPI refused.

Accordingly, Roquette requests that the Court issue an Order compelling SPI to produce the requested relevant information in each of the above-listed categories.

Respectfully,


Julia Heaney

cc: Dr. Peter Dalleo, Clerk (By e-filing)
John W. Shaw (By e-mail)
Oren D. Langer (By e-mail)

EXHIBIT 1

YOUNG & THOMPSON

International Patent & Trademark Law

Established 1903

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1875-1936

William H. Young
1902-1958

Irvin S. Thompson
1903-1979



July 20, 2007

Oren D. Langer
Morgan, Lewis & Bockius LLP
101 Park Avenue
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Via Electronic Mail and Federal Express

Re: *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540 (***)
Our Ref. 0600-269

Dear Oren,

This follows our earlier letter of June 6, 2007, in which we identify with specificity the substantial omissions from SPI's interrogatory responses. In particular, we requested that SPI supplement its response to each of Interrogatories 1-4, 6, 7 and 11-13.

On June 15, 2007, SPI responded to our letter, indicating that it would supplement its interrogatory responses before the end of the following week. On June 22, 2007, SPI supplemented only some of its responses, leaving our expressed concerns regarding Interrogatory Nos. 4, 7 and 11 unaddressed.

Even as to those interrogatories which SPI did attempt to address, its supplemental responses remain deficient and fail to comply with the Federal Rules.

SPI has provided no further response. Accordingly, we request again that SPI immediately supplement its interrogatory responses to provide the requested information.

The following interrogatories were identified in our original June 6th letter, and SPI's response in each remains deficient, or non-responsive.

Interrogatory No. 1

SPI still has not provided a modicum of information relating to the physical and/or chemical properties of any SPI spray-dried mannitol product other than Mannogem EZ, despite the fact that [REDACTED]

[REDACTED] We note, for example, SPI 5776, 5786 and 6192.

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July 20, 2007

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The patent-in-suit encompasses, *inter alia*, certain mannitol products and compositions having the recited features. Information regarding any dry form (pulverulent) mannitol that is produced by spray drying, including atomization, is directly relevant to Roquette's infringement claims.

SPI's supplemental response, stating merely that "SPI Pharma states that its current mannitol product line is publicly available information that is provided on SPI Pharma's website," is inadequate. Moreover, that supplemental response doesn't even attempt to address spray-dried mannitol products, if any, that are no longer part of SPI's "current mannitol product line."

Roquette renews its request for this information.

Interrogatory No. 2

SPI apparently refuses to provide Roquette with meaningful sales and profit data, from which Roquette can reasonably calculate its damages. SPI's generic statement that it has sold Mannogem EZ continuously since 2001, and the scarce, intermittent documents reflecting a few isolated sales over that 6-year time frame, amounts effectively to a refusal to provide the requested sales and profit information.

Roquette renews its request for this information.

Interrogatory No. 4

Roquette's request of June 6, 2007 that SPI answer this interrogatory has been ignored. Information related to whether SPI has received any opinions of counsel regarding the '777 patent is directly relevant to SPI's willfulness.

Roquette renews its request for this information.

Interrogatory Nos. 7 and 11

Roquette's request of June 6, 2007 that SPI supplement its response to this interrogatory has been virtually ignored. SPI's June 15th letter and June 22 supplemental responses make no mention of these interrogatories. Despite SPI's indication during the July 9th teleconference that it intended to supplement its response, we have since received no communication.

These interrogatories seek, *inter alia*, SPI's facts and bases regarding its counterclaim and affirmative defense that the '777 patent is invalid. In its only response to date, SPI does nothing more than identify the same patents that are identified in the patent itself, along with a few foreign counterparts to those patents.

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July 20, 2007
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Given that SPI filed its counterclaim, alleging invalidity based on four distinct statutes, SPI presumably has, and indeed is expected to have, some good faith basis in fact and law for its invalidity claim and defense. *See* Fed.R.Civ.P. 11(b).

Roquette renews its request for this information.

Considering SPI's already extended delay in responding to the foregoing requests, we look forward to your prompt reply and SPI's meaningful supplementation of its interrogatory responses.

To the extent that you do not intend to reply, or SPI does not intend to supplement its responses, please consider this our request to schedule a meet-and-confer teleconference to discuss the issues discussed in this letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey R. Snay", with a long horizontal flourish extending to the right.

Jeffrey R. Snay

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July 30, 2007

VIA E-MAIL AND FEDERAL EXPRESS

Jeffrey R. Snay, Esq.
Young & Thompson
745 South 23rd Street
Arlington, Virginia 22202

Re: *Roquette Freres v. SPI Pharma, Inc. and Drytec Ltd.*, Civ. No. 06-540 (***)
Client-Matter No. 059717-3025

Dear Jeffrey:

I write in response to your letter dated July 20. SPI Pharma strongly disagrees with your characterization of SPI Pharma's initial and supplemental interrogatory responses, which were more than adequate under the Federal Rules given the limited discovery provided by Roquette, the plaintiff in this patent infringement lawsuit.

Interrogatory No. 1

Roquette has identified only one accused product in its complaint, *viz.*, Mannogem™ EZ. Based on Roquette's failure to explain or document its infringement position concerning Mannogem™ EZ in response to SPI Pharma's Interrogatory Nos. 2, 7 and 12 and Document Request Nos. 5-8, we can only conclude that Roquette does not have a good faith basis for its allegations of infringement against that product, much less any other SPI Pharma spray-dried mannitol product. In the absence of a specific showing of relevance to infringement, Roquette is not entitled to conduct a "fishing expedition" for discovery concerning any other SPI Pharma product. If Roquette believes that SPI Pharma sells another spray-dried mannitol product that infringes the '777 patent, it can obtain the product in the market place and test it just as Roquette did for the Mannogem™ EZ product. It is Roquette's burden to establish a good faith basis for making any infringement allegations against any SPI Pharma product. Fed. R. Civ. P. 11(b). It is not SPI Pharma's burden to produce discovery based on Roquette's unsupported speculation.

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SPI Pharma also disagrees with Roquette's broad characterization of its claimed invention as covering "certain mannitol products" and its assertion that information "regarding *any* dry form (pulverulent) mannitol that is produced by spray drying, including atomization, is directly relevant to Roquette's infringement claims." (emphasis added). On the contrary, Roquette's '777 patent claims are very specific, including a specific friability range, apparent density, particle size and rate of dissolution. The claims also recite detailed test methods and requirements to assay friability range and dissolution rates. Any allegedly infringing spray-dried mannitol product must meet all of these specific elements of the '777 patent claims. To date Roquette has not shown the slightest basis for alleging that any SPI Pharma product meets those claim elements, including Mannogem™ EZ.

SPI Pharma's response to Interrogatory No. 1 is more than adequate, and we do not believe Roquette is entitled to any further response regarding any other SPI Pharma spray-dried mannitol product.

Interrogatory No. 2

SPI Pharma has produced relevant, non-privileged documents pertaining to sales of Mannogem™ EZ since its commercial launch in November 2001. These documents are identified in SPI Pharma's supplemental response (SPI 05491-710, SPI 05850-65, SPI 06792-816) and contain the sales and profit information requested by Roquette. To the extent more current sales figures are gathered by SPI Pharma sales and marketing personnel, SPI Pharma will supplement its response to Interrogatory No. 2 accordingly.

Interrogatory No. 4

SPI Pharma has not "ignored" answering Roquette's Interrogatory No. 4. SPI Pharma objected that this interrogatory was premature and that Roquette sought information protected by the attorney-client privilege, work-product doctrine, or other applicable privilege. To the extent SPI Pharma received an opinion of counsel, any such opinion will be identified on SPI Pharma's privilege log, on the date we agree to exchange privilege logs, and/or in response to Interrogatory No. 4.

Interrogatory Nos. 7 and 11

SPI Pharma's responses to Roquette's Contention Interrogatory Nos. 7 and 11 are more than adequate given the early stage of discovery (*e.g.*, no depositions have been taken and there has been minimal document production by Roquette). *See Fischer and Porter Co. v. Tolson*, 143 F.R.D. 93, 95 (E.D. Pa. 1992) ("[t]he interests of judicial economy and efficiency for the litigants dictate the 'contention interrogatories are more appropriate after a substantial amount of discovery has been conducted.'") (quoting *Nestle Foods Corp. v. Aetna Cas. and Sur. Co.*, 135 F.R.D. 101, 110-111 (D.N.J. 1990)); *In re Convergent Technologies Securities Litigation*, 108

Morgan Lewis
C O U N S E L O R S A T L A W

Jeffrey R. Snay, Esq.
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F.R.D. 328, 338 (courts are skeptical about the quality of the information that early responses to contention interrogatories are likely to contain).

If Roquette is interested in receiving contention discovery, then Roquette, as plaintiff bearing the initial burden of proof, need to first answer SPI Pharma's contention Interrogatory Nos. 2, 7 and 12 requesting that Roquette explain its infringement contention in detail. Roquette is obligated to show which patent claims it contends are infringed and provide the factual and legal bases for its allegations, including an element-by-element claim chart specifying its infringement allegations. *S.S. White Burs, Inc. v. Neo-Flo, Inc.*, Civ. Action No. 02-3656, 2003 U.S. Dist. Lexis 7718, *4 (E.D. Pa. May 2, 2003) ("A plaintiff may be questioned as to which patent claims it contends are infringed....[C]ourts will postpone to the end of discovery the responses of 'contention interrogatories,' which ask a party to state all facts and theories upon which it bases a contention, so that the party does not have to articulate theories of its case which are not yet fully developed."). As appropriate, SPI Pharma would respond thirty days after receiving Roquette's detailed explanation of its patent infringement contentions with its contention interrogatory responses setting forth its explanation of the bases for patent invalidity.

We are prepared to conduct a meet-and-confer teleconference to discuss Roquette's and SPI Pharma's interrogatory responses and document production issues. Please provide a specific date and time either later this week or sometime next week, and we will let you know of our availability.

Sincerely,



Oren D. Langer

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Emil Bönnelycke
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William H. Young
1902-1958

Irvin S. Thompson
1903-1979



August 17, 2007

Oren D. Langer
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New York, NY 10178-0060

Via Electronic Mail and Federal Express

Re: *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540 (***)
Our Ref. 0600-269

Dear Oren,

This follows our meet and confer teleconference of earlier today, and serves to chronicle the parties' stated positions regarding Roquette's concerns over SPI's failure to produce requested discovery.

I. Interrogatory No. 1: SPI's Spray-Dried Mannitol Products

Roquette reiterated its longstanding request for information, including physical and chemical properties, of all SPI's spray-dried mannitol products. As stated in our letter of July 20, 2007, [REDACTED]

[REDACTED] The patent-in-suit covers, *inter alia*, mannitol products that exhibit properties that are obtained by spray-drying. Given that Roquette has obtained test data indicating that one spray-dried mannitol product manufactured by Drytec for SPI infringes the patent-in-suit, Roquette reasonably believes that other spray-dried mannitols produced by or for SPI also likely infringe, especially those spray-dried mannitol products that were manufactured at the same Drytec facility, or are now manufactured by SPI using the same or similar spray-drying system.

SPI refuses to provide information on any spray-dried mannitol product other than MannogemTM EZ.

II. Interrogatory No. 2: SPI's Sales and Profit Information

Roquette reiterated its concern that the documents produced by SPI in response to this request are inadequate to reasonably calculate Roquette's damages.

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Oren D. Langer
August 17, 2007
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In its July 30, 2007 response to Roquette's July 12th letter, SPI identified three blocks of produced documents that SPI contends are responsive and, with respect to MannogemTM EZ, "contain the sales and profit information requested by Roquette." The largest block, SPI 05491-710, is almost entirely redacted.

Nonetheless, SPI represented that the documents identified in its July 30, 2007 letter are complete through May 2007, and are sufficient for calculation of damages with respect to MannogemTM EZ through May 2007.

Roquette accepts SPI's representations regarding this category, but reserves the right to seek documentary information from which SPI 5850-65 was compiled.


III. Interrogatory No. 7: SPI's Invalidity Contentions

Roquette reiterated its request for SPI's explanation of its invalidity contentions. In its answers to Roquette's first and second amended complaints, SPI alleges that the patent-in-suit is "invalid for failure to satisfy the conditions of patentability specified in Title 35, U.S.C. §§ 101, 102, 103 and 112." To date, SPI's only response to Roquette's contention interrogatory is a list of the same patents that are identified in the patent itself, along with a few foreign counterparts to those patents.

Roquette requested that the parties simultaneously exchange invalidity and infringement contentions on Wednesday, August 22, 2007. SPI rejected Roquette's request.

The parties each identified available dates for a discovery dispute teleconference with the Court, and agreed that Roquette would contact the Court on Monday, August 20th, to schedule such a conference.

Sincerely,



Jeffrey R. Snay

EXHIBIT 2

Redacted in its Entirety

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on September 4, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

John W. Shaw
Jeffrey T. Castellano
YOUNG, CONAWAY, STARGATT & TAYLOR
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19899-0391

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on September 4, 2007 upon the following individuals in the manner indicated:

BY E-MAIL

John W. Shaw
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Wilmington, DE 19899-0391

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/s/ Benjamin J. Schladweiler

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